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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,851	09/09/2003	Christopher J. Murphy	TPLANT-08360	2123
72960	7590	04/04/2008	EXAMINER	
Casimir Jones, S.C. 440 Science Drive Suite 203 Madison, WI 53711			LIU, SAMUEL W	
			ART UNIT	PAPER NUMBER
			1656	
			MAIL DATE	DELIVERY MODE
			04/04/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/657,851	<b>Applicant(s)</b> MURPHY ET AL.	
	<b>Examiner</b> SAMUEL W. LIU	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 53-67 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 53-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### *Status of claims*

Claims 53-67 are pending.

The amendment filed 1/16/08 which amends claims 53 and 66-67, and cancels claims 1-52 has been entered. The applicants' request filed 1/16/08 for extension of time of three months has been entered. Claims 53-67 are examined in this Office action.

### ***Maintained-Claim Rejections - 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 53, 56, 59-60, 63 and 66 remain rejected under 35 U.S.C. 102(b) as being anticipated by Kwock et al. (*J. Nutr.* (1984) 114, 1451-1461).

Kwock et al. teach a cow milk composition comprising ferric iron bound lactobionate (see Table 3, page 1457). Since the cow milk contains the average level of IGF-1 of 3.7 ng/ml (see "*Discussion of art*"[1] cited in the Office action mailed 7/17/07), Kwock et al. inherently teach the composition of claim 53.

\* Examiner note: (i) structure of the "recombinant insulin-like growth factor" is considered to be the same as that of non-recombinantly produced insulin-like growth factor as the structural property of the claimed product is not altered by the means of producing said

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product; and (ii) “for organ preservation” in claim 53 refers to an intended use which has no patentable weight.

Because the milk comprises the antimicrobial peptide, e.g., nisin, in the milk (see “*Discussion of art*”-2), the above Kwock et al. teaching inherently anticipates claim 56.

The nisin peptide in said milk is about 0.045 mg/ml (45 ng/ml) (see “*Discussion of art*”[2] cited in the Office action mailed 7/17/07), which anticipates claim 59.

Since the raw milk comprises nerve growth factor (see “*Discussion of art*” [3] cited in the Office action mailed 7/17/07), the above Kwock et al. teaching inherently anticipates claim 63.

Since Ferric iron bound lactobionate has 17.1% retention in the cow’s milk (see Table), and since the cow’s milk contains 0.15 mg/100 ml (see “*Discussion of art*”-4) and iron has molecular weight of 55.84, the result of calculation  $([0.15/100/55.84] \times 17.1\% \text{ mole in } 1000 \text{ ml})$  is ~ 4.6 mM, which inherently anticipates claim 60 and 66.

*The applicants’ response to the rejection under 35 USC 102*

The response filed 1/16/08 argues that the applicants have amended the claims to indicate that the insulin-like growth factor-1 (IGF-1) is recombinant. As result, the claims are not anticipated. Also, the response asserts that the 102 reference does not teach the composition comprising the claimed recombinant IGF-1 and lactobionate.

The applicants’ arguments are found unpersuasive because, as discussed above, the Kwock et al. cow milk composition inherently anticipates instant composition comprising the “ferric iron bound lactobionate and “IGF-1”, which is considered to be structurally identical to the "recombinant" IGF-1 (for the reason, see above). Thus, the rejection is maintained.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragton, can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Karen Cochrane Carlson, Ph.D./

Primary Examiner, Art Unit 1656

/Samuel W Liu/Ph.D.

Examiner, Art Unit 1656

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